IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

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ANNIE TUMMINO, *et al.*,

Plaintiffs,

No. 12-CV-0763 (ERK/VVP)

v.

MARGARET HAMBURG, *et al.*,

Defendants.

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**PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR ATTORNEYS' FEES AND COSTS**

## INTRODUCTION

Plaintiffs seek an award of attorneys' fees and costs for work performed in this highly complex and exceptional challenge under the Administrative Procedures Act (APA) which was necessitated by and ultimately remedied Defendants' corruption of the administrative process for over a decade concerning the over-the-counter status of emergency contraception. Plaintiffs fought over a 12-year period to remedy the unlawful government interference and undue delays in the administrative process amounting to an "administrative agency filibuster," involving eight years of cumulative litigation in two District Court cases and an appeal to the Second Circuit. Plaintiffs successfully obtained injunctive relief under the APA requiring the Food and Drug Administration (FDA) and Health and Human Services to grant a Citizen Petition for unrestricted over-the-counter access to emergency contraception. Defendants had improperly denied the Citizen Petition twice, and it was Plaintiffs' efforts that resulted in the removal of all scientifically unsupported, arbitrary, capricious and unlawfully politically motivated age and

point-of-sale restrictions enacted by the government to obstruct over-the-counter access to emergency contraception. *Tummino v. Hamburg* (hereinafter "*Tummino II*"), No. 12-CV-763 (ERK)(VVP), 2013 U.S. Dist. Lexis 49666, *87, 101-02, 105-06 (E.D.N.Y. April 5, 2013). Plaintiffs' tenacious and skilled litigation of this case resulted in success which has removed unlawful political interference from the science-based federal drug approval process and positively impacted the reproductive health and lives of millions of women and girls around the United States who now have timely access to emergency contraception to avoid the risk of unintended and unwanted pregnancy.

As established below, Plaintiffs satisfy all statutory requirements for an award of fees and costs under the Equal Access to Justice Act (EAJA), 28 U.S.C. § 2412. Plaintiffs indisputably are prevailing parties, and neither the government's pre-litigation conduct, nor its litigation position, were substantially justified. Moreover, the government's claims in this litigation were without any legal or factual basis and were made for improper purposes, including delay and political interference with the drug approval process. Therefore, having achieved excellent success in this action, Plaintiffs are entitled to their reasonable attorneys' fees and costs expended in this case pursuant to the EAJA, 28 U.S.C. § 2412.[1]

## PROCEDURAL AND FACTUAL BACKGROUND

This Court is familiar with the underlying facts of this case which are set forth in detail in the Court's opinions in *Tummino v. Torti* (hereinafter "*Tummino I*"), 603 F. Supp. 2d 519, 540

[1] Plaintiffs' Motion for Attorneys' Fees and Costs, and for Enlargement of Time to File Petition or, Alternatively, to Stay This Motion Until Resolution of all Post-Judgment Requests for Relief was filed on May 9, 2013. (ECF No. 97.) Plaintiffs hereby incorporate that motion by reference with appropriate amendments to the estimates of the reasonable number of hours and costs as was noted in the motion. Plaintiffs have also, contemporaneously with this memorandum, filed a Notice of Motion *nunc pro tunc*.

(E.D.N.Y. 2009),[2] *Tummino II*, at *4-18, and *Tummino v. Hamburg* (hereinafter "*Tummino III*"), No. 12-CV-763 (ERK)(VVP), 2013 U.S. Dist. Lexis 67019, *3-9 (E.D.N.Y. May 10, 2013). Accordingly, Plaintiffs provide an abbreviated set of facts and proceedings here for purposes of this motion. The facts and proceedings in *Tummino I* are reviewed here for context, but Plaintiffs are only seeking compensation here for work completed after *Tummino I*, post-remand to present.

Over the last 12 years, Defendants engaged in a pattern of arbitrary and capricious conduct ultimately culminating in the improper denial of the Citizen Petition seeking unrestricted over-the-counter status for Plan B – the original two-pill emergency contraceptive product – and all drugs that are equivalent to Plan B. *Tummino III*, at *5. For over a decade, the FDA failed to properly consider scientific evidence that supported unrestricted over-the-counter approval of levonorgestrel-based emergency contraception for all ages and without any point-of-sale requirements. *See Tummino II*, at *12 (the FDA's Center for Drug Evaluation and Research has concluded that "Plan B One-Step should be approved for nonprescription use for all females of child-bearing potential") (internal quotation marks omitted); *Tummino I*, at 528-34 (citing FDA 2003 advisory committee vote 23-4 to recommend "Plan B for over-the-counter status without age or point-of-sale restrictions," unanimous vote that "Plan B is safe for use in a non-prescription setting," and history of FDA review staff scientific findings to approve over-the-counter access without restriction).

The effort to bring these products over-the-counter began in 2001, when Plaintiff Association of Reproductive Health Professionals and others filed a Citizen Petition asking the

[2] By Order dated March 6, 2013, ECF No. 78, the Court amended its opinion of March 23, 2009. Unless otherwise specified, citations to *Tummino I* refer to sections of the opinion that were not altered by the Court's March 6, 2013, Order and to the published version of the opinion in the Federal Supplement.

FDA to switch Plan B "and any new drug eligible for filing an abbreviated new drug application because of its equivalence to . . . Plan B" from prescription only to over-the-counter status. Citizen Petition (Feb. 14, 2001), ECF No. 95 at 8; *Tummino I*, at 526. For most of the time that the Citizen Petition was pending, the FDA considered various requests from the manufacturer of Plan B and subsequently, Plan B One-Step, known as supplemental new drug applications (SNDAs), to put their products over-the-counter. Throughout these proceedings, Defendants "inextricably tied" the consideration of the Citizen Petition with the SNDAs. *See Tummino I*, at 523, 543; *see also Tummino II*, at *73-74, 86-87.

In 2005, after four years of inaction, Plaintiffs brought this litigation to compel the FDA to make a decision whether to grant or deny the Citizen Petition. In June of 2006, the FDA denied the Citizen Petition. *Tummino I*, at 536. Even though the FDA had effectively made a decision on the Citizen's Petition at the time it denied the Plan B sponsor's first SNDA, it waited almost three years (and only after this lawsuit was filed) to communicate that decision to Plaintiffs. *Id.*, at 536-37. The record is clear that from early on the process was tainted by improper political interference which "significantly affect[ed]" FDA's decision-making on the over-the-counter switch, including "pressure coming from the White House." *Id.*, at 529.

The lawsuit uncovered numerous examples of significant departures from FDA policies and procedures as to both the Citizen Petition and the SNDAs. For example, despite the fact that the FDA had helped craft the actual use[3] study performed by the Plan B sponsor in connection with its first SNDA, the FDA subsequently denied that application largely on the grounds that

[3] An actual use study simulates over-the-counter use of a product to predict if a drug will be used correctly by the target population. *Tummino II*, at *43-44, citing Decl. of Cynthia C. Harper, Ph.D. in Support of Pls.' Mot. for Prelim. Inj. and Summ. J. (Feb. 16, 2012) ¶ 5, ECF No. 3 at 2-3. The FDA typically does not require subjects of any particular age to be included in actual use studies, *Tummino II*, *41-42 (citations omitted), rather, "the Agency has a long history of extrapolating findings from clinical trials in older patients to adolescents." *Tummino I*, at 527 (internal quotation marks omitted).

the study was inadequate. *Tummino I*, at 526, 532. The evidence also showed that the decision to deny the Plan B SNDA was made by the Commissioner "*before* FDA staff had completed their scientific reviews of the data." *Id.*, at 530.

In August 2006, the FDA approved a SNDA to make Plan B available over-the-counter for consumers 18 and older, creating an unprecedented dual-tier marketing regime under which women needed either government-issued photo-identification or a prescription to access the product. *Id.*, at 536. "At the FDA's insistence, the sponsor agreed to . . .distribute the product only to licensed pharmacists, and to direct pharmacies to keep Plan B behind-the-counter." *Id.* This decision was one among many "suspect" moves. *Id.*, at 523, 546 ("[T]he evidence strongly suggests that even the decision to permit the OTC [over-the-counter] sale of Plan B to women over the age of 18 was made solely to facilitate the confirmation of Dr. von Eschenbach as Commissioner of the FDA.").

Based on this record, in 2009, the District Court concluded that the FDA's denial of the Citizen Petition was "arbitrary and capricious" and "not the result of reasoned and good faith agency decision-making." *Id.*, at 523. The Court remanded to the agency to reconsider the Citizen Petition, but directed the FDA "to make Plan B available to 17 year olds without a prescription," finding that "[a] remand would serve no purpose" because the exclusion of 17 year olds "runs counter to the evidence and is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*, at 549-50 (internal quotation marks omitted).

On remand, prior to the filing of *Tummino II*, Defendants engaged in the same bad faith that had preceded the District Court's 2009 decision. *Tummino II*, at *10-13. Causing further undue delay of almost three years, the FDA refused to take any steps to reconsider the Citizen

Petition. *Id*. Instead, the agency informed Plaintiffs that it believed that "the best way" to comply with the order was "to review a supplemental new drug application expected to be submitted by the sponsor of [Plan B One-Step]" for over-the-counter access for all ages. *See* Letter from Frank Amanat to Suzanne Novak (Aug. 13, 2010), Case No. 05-CV-366 (ERK/VVP), ECF No. 307-3.

In November 2010, Plaintiffs filed a motion to hold Defendants in contempt based on the FDA's failure to make any meaningful efforts to comply with the Court's Order directing it to reconsider its denial of the Citizen Petition. (ECF No. 307.)

Less than one day before Plaintiffs' Motion for Contempt was scheduled to be heard by the Court, the FDA denied the Citizen Petition. (ECF No. 2 at 25.) Just prior to the hearing, the FDA had recommended approval of the Plan B One-Step SNDA because "science-based evidence" established that the drug is "safe and effective and should be approved for nonprescription use for all females of child-bearing potential." *Tummino II*, at *12 (quoting Statement from FDA Commissioner Margaret Hamburg, M.D., on Plan B One-Step (Dec. 7, 2011), Pl. Add. 36). However, in a wholly unprecedented move, Health and Human Services Secretary Kathleen Sebelius overruled this decision on December 7, 2011, for reasons that the Court determined in *Tummino II* were "obviously political." *Tummino II*, at *20-23. Although the FDA had previously indicated to the Court that it would indefinitely defer reconsider ruling on the Citizen Petition because it believed a decision on the Plan B One-Step SNDA would satisfy the Court's Order, (ECF No. 315, Defs' Mem. of Law in Opp. to Pls.' Mot. for Civil Contempt, at 20-24), the government scurried at the eleventh hour to re-rule on the Citizen Petition before having to appear in Court on Plaintiffs' Motion for Contempt. (ECF No. 2 at 25.)

Based on this turn of events, at the motion hearing for contempt, Plaintiffs asked to add Secretary Sebelius as a Defendant and amend their allegations to include the actions taken concerning the Citizen Petition and the SNDA. The Court directed that the case should be re-opened – *Tummino II* was filed.

Plaintiffs filed a Supplemental Complaint, and Motions for Preliminary Injunction and Summary Judgment, seeking an order directing Defendants to permit the drug sponsors of levonorgestrel-based emergency contraceptives, and any drug eligible for filing an abbreviated new drug application because of its equivalence to Plan B or Plan B One-Step, to make these products available over-the-counter without age or point-of-sale restrictions. (ECF Nos. 2, 14.) In essence, Plaintiffs argued that the denial of the Citizen Petition was based on significant departures from agency policy and procedure, implausible justifications, and improper political interference that the Court had previously found to be arbitrary, capricious and made in bad faith in *Tummino I*. *Id.*

Defendants filed a Motion to Dismiss the Fifth Amended and First Amended Supplemental Complaint in which they raised identical arguments – previously rejected by this Court in *Tummino I*, at 539-42 – that Plaintiffs lacked standing to challenge the FDA's denial of the Citizen Petition and that the Court lacked jurisdiction to review the FDA or the Secretary's decision making process concerning the Plan B One-Step SNDA. (ECF No. 42.) Once again, these arguments were rejected by the Court. *Tummino II*, at *10, n.3. Subsequently, Plaintiffs filed a Second Amended Supplemental Complaint, adding adolescents under the age of 17. (ECF No. 56-2.) Defendants filed yet another Motion to Dismiss (ECF No. 62.), that was also denied. (ECF No. 62.) Despite the fact that Defendants had argued to this Court that a Plaintiff would need to be under seventeen to have standing (Tr. of April 27, 2012, 140:1-11), Defendants

persisted in rehashing old arguments including, for example, that 14-year old Anaya Kelly did not have standing. (ECF No. 62.)[4]

Plaintiffs also had to expend resources to respond to a Motion to Intervene by the drug manufacturer of Plan B One-Step, Teva Women's Health, Inc. (Teva). This required addressing the issues created by Teva's role in the over-the-counter approval process, including its ongoing discussions with Defendant FDA concerning its SNDA for Plan B One-Step and various concessions made with Defendants in age and point-of-sale restrictions by the manufacturer which were inconsistent with Plaintiffs' position. Plaintiffs were only advised of the decisions resulting from these discussions concerning Teva's SNDA when it was convenient for Defendants. Teva was ultimately denied intervenor status and deemed an *amicus curiae* by the Court. (ECF No. 86.)

Plaintiffs were also required to review what the government filed as the administrative record in this case in July 2012. (ECF Nos. 69, 69-1 to 69-7.)

The Court also issued an Order to Show Cause at oral argument in December 2011 after noting that to deny emergency contraception access over-the-counter to those consumers about whom Defendants have not even expressed concerns, and for whom the data, on its face, shows that the standards for over-the-counter access have been met, "would be the height of arbitrariness." (Tr. of Dec. 13, 2011, Hearing, 27:18-28:3, Case No. 05-CV-366 (ERK/VVP).) The Order to Show Cause (OTSC) focused on the question as to "why the FDA should not be directed to make Plan B available to those persons whom the studies submitted to the FDA demonstrate are capable of understanding when the use of Plan B is appropriate and the

[4] The government's argument regarding standing is further evidence of bad faith. It was the government's position that one of the Plaintiffs must be under 17, when due to the government's extraordinary delay Plaintiffs who were as young as 14 during *Tummino I* had reached the age of majority when *Tummino II* commenced. (Tr. of April 7, 2012, 139:10-142:14.) *See Tummino I*, Angelica Jaffe Decl. ECF. No. 259 at 5.

instructions for its use," see Minute Order, *Tummino v. Hamburg*, Case No. 05-cv-366 (Feb. 16, 2012). Plaintiffs' were granted leave to respond to Defendants' response to the OTSC. (ECF Nos. 27-30, 36.)

Plaintiffs had to oppose Defendants' Cross-Motion for Summary Judgment in which Defendants' primary and unsuccessful argument was that it is not FDA policy to extrapolate data from adults to pediatric populations, and decisions about whether extrapolation is appropriate are a matter of scientific judgment depending on data and circumstances presented in each application. (ECF No. 71.) Defendants made these arguments concerning extrapolation even though the Court had addressed this issue in *Tummino I* and found "evidence of the lack of good faith is also confirmed by the manner in which the FDA departed from its normal procedures for evaluating the OTC switch applications when it considered the Plan B applications[,]" including "the FDA's refusal to extrapolate actual use study data from the older age group to the 16 and younger age group. There is evidence in the record that the FDA routinely extrapolated such data when reviewing the safety and effectiveness of various other contraceptives." *Tummino I*, at 526-27, 528-29, 531-34, 547-48.

Ultimately, the Court granted Plaintiffs' Motion for Summary Judgment and denied Defendants' Cross-Motion for Summary Judgment. (ECF Nos. 85, 87.)

The denial of the Citizen Petition was inevitable after Defendant Sebelius ordered the FDA to reject the SNDA because the data that the Secretary (unreasonably) found lacking in the SNDA was also lacking in the Citizen Petition. *Tummino II*, at *18-19; *Tummino III*, at *5-6. The District Court additionally found the FDA's denial of the Citizen Petition was "unsound" based on numerous significant departures from agency policies and failures to acknowledge and consider relevant data within its possession. *Tummino II*, at *72-87. These facts led the Court

to conclude, based on an extensive factual record, that Defendants arbitrarily, capriciously and unreasonably denied the Citizen Petition – for a second time – based on actions and decisions that were "politically motivated, scientifically unjustified, and contrary to agency precedent." *Tummino II*, at *86.

Accordingly, the Court remanded with directions that Defendants, "grant the Citizen Petition and make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within thirty days." *Id.*, at 181-82.

Just prior to the expiration of the Court's 30 day deadline and contrary to the Court's directive, the FDA announced that it had approved an amended SNDA allowing Plan B One-Step to be sold on the shelf in retail locations with an on-site pharmacy, without a prescription, to those 15 and older with proof of age. *Tummino III*, at *10-12. As a result of this change, Plan B One-Step would not be available by prescription to anyone. All other levonorgestrel products remained subject to the restrictions imposed on Plan B – they could only be sold behind-the-counter at pharmacies, to women 17 and older with government-issued photo identification and to all others only by prescription. *Id.*, 10-13. The day after the FDA approved Teva's amended SNDA, Defendants filed a Notice of Appeal of this Court's Order. (ECF No. 92.) Defendants then moved for a stay pending appeal, attempting to rely on its approval of Teva's amended SNDA to show that "no plaintiff will be harmed by a stay." *Id.* Plaintiffs had to litigate Defendants' last minute Motion for a Stay. (ECF Nos. 91-93, 95.) This Court rejected that argument in its Order denying the Motion for Stay, finding that the approval was "intended to provide sugarcoating for the FDA's appeal." *Tummino III*, at *11-12.

Plaintiffs then had to oppose Defendants' appeal of the denial of their Motion for a Stay. In denying a stay, the U.S. Court of Appeals for the Second Circuit agreed with this Court on

June 5, 2013 "insofar as the [district court] order mandates immediate over-the-counter access to the two-pill variants of emergency contraceptives, a stay is denied because the Appellants have failed to meet the requisite standard. *See McCue v. City of N.Y.* (*In re World Trade Ctr. Disaster Site Litig.*), 503 F.3d 167, 170 (2d Cir. 2007)." Doc. 85, Case No. 13-1690, U.S. Court of Appeals for the Second Circuit. Following Defendants' unsuccessful Motion for a Stay in the Second Circuit, this Court approved Defendant's plan to comply with the Court's Order and recognized it was the Plaintiffs alone who were responsible for the outcome in this case in making emergency contraception over-the-counter without age or point-of-sale restrictions. (ECF No. 106 at 6.)

The parties filed a Stipulation with the U.S. Court of Appeals for the Second Circuit providing that Defendants voluntarily dismissed, with prejudice, the appeal of this Court's April 5, 2013, Memorandum and Order and Final Judgment and that Plaintiffs would seek fees and costs, including related to the appeal, from the United States District Court for the Eastern District of New York to the extent available under the EAJA, 28 U.S.C. § 2412, or under any other appropriate statute or authority and that Defendants may oppose any such petition. Docs. 95 & 102, Case No. 13-1690, U.S. Court of Appeals for the Second Circuit.

## ARGUMENT

### I. Plaintiffs Meet EAJA Requirements For a Fee Award

#### A. Plaintiffs are "Prevailing Parties"

Plaintiffs are entitled to attorneys fees under the EAJA if they are prevailing parties in the litigation. 28 U.S.C. § 2412(d). Plaintiffs are considered the prevailing party for purposes of attorneys' fees if they succeed "on any significant issue in the litigation which achieves some of the benefit the parties sought in bringing the suit." *Hensley v. Eckerhart*, 461 U.S. 424, 433

(1983). Plaintiffs are, without any question, prevailing parties in this litigation on their APA claim based on the Court's April 5, 2013, Memorandum and Order in *Tummino II* and the judgment of this Court entered on April 10, 2013. (ECF No. 87.)

This Court granted injunctive and substantive legal relief in two respects on Plaintiffs' main claim under the APA in this litigation: (1) the Court determined that Plaintiffs had established their central legal claim, by holding that the government's actions were arbitrary, capricious and abuse of discretion, and (2) the Court granted Plaintiffs' substantive relief on the merits of their claims, by remanding the case to the FDA with "the instruction to grant the Citizen Petition and make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within thirty days." *Tummino II*, at *86, 101-02.

### B. The Government's Position in this Case was not Substantially Justified

Under the EAJA, a prevailing party shall be awarded fees unless the government can prove that its position was "substantially justified." 28 U.S.C. § 2412(d)(1)(A). To establish that its position was substantially justified, the government must prove that both the agency's underlying conduct at issue in the litigation and its litigation position were substantially justified.[5] 28 U.S.C. § 2412(d)(2)(D) ("position of the United States" is defined as " in addition to the position taken by the United States in the civil action, the action or failure to act by the agency upon which the civil action is based."); *see Comm'r, INS v. Jean*, 496 U.S. 154, 159 (1990); *see also Trichilo v. Sec'y of Health and Human Services*, 823 F.2d 702, 708 (2d Cir.

[5] Once a determination that the government's position lacks substantial justification has been made, "a fee award presumptively encompasses all aspects of the civil litigation," including litigation to recover fees. *Comm'r, INS v. Jean*, 496 U.S. 154, 160-61 (1990). Plaintiffs' entitlement to fees also includes any fees and expenses reasonably incurred in connection with the vindication of rights related to any appeal. *Trichilo v. Secretary of Health and Human Services*, 832 F.2d 743, 745 (2d Cir. 1987), citing *Trichilo v. Sec'y of Health and Human Services*, 823 F.2d 702, 707-08 (2d Cir. 1987).

1987). This must be accomplished by a "strong showing." *Environmental Def. Fund v. Watt*, 722 F.2d 1081, 1085 (2d Cir. 1983) (citations omitted). To meet this burden, the government must show that its position had a reasonable basis in both law and fact. *Pierce v. Underwood*, 487 U.S. 552, 565 (1988). A finding that either the government's underlying conduct or its litigation position was not substantially justified is sufficient to support an award under the EAJA. *Environmental Def. Fund*, 722 F.2d at 1085-86.

The Court's well reasoned and detailed opinion in *Tummino II* establishes how the government's pre-litigation and litigation position concerning the denial of the Citizen Petition on remand lacked substantial justification. Based on a thorough and careful review of the extensive factual record in this case and the legal arguments raised by Defendants, the Court found the Defendants' actions in denying the Citizen Petition were arbitrary, capricious, contrary to agency precedent, taken for improper political reasons and in bad faith in violation of the APA.

As the court noted, because the SNDA and Citizen Petition "were clearly linked together" by the Defendants, once the Secretary unlawfully directed the FDA to deny the Plan B One-Step SNDA, the FDA had no possible basis on which to approve the Citizen Petition. *Tummino II*, at *63-64. Under these circumstances, it was not possible to exercise meaningful judicial review over the denial of the Citizen Petition without considering the propriety of the Secretary's actions regarding the SNDA because the FDA's own justification for its denial of the Citizen Petition indicated a substantial reliance on the SNDA process. *Id.* The government's denial of the SNDA and the Citizen Petition, lacking a reasonable basis in fact or law, was accomplished by significant unexplained departures from a number of established policies and practices followed by the FDA. Furthermore, the Secretary's unprecedented "directive to the FDA to reject the Plan

B One-Step SNDA forced the agency to ride roughshod over the policies and practices that it has consistently applied in considering applications for switches in drug status to over-the-counter availability." *Tummino II*, at *18-87.

The Court was clear as to the ways the government's actions concerning the SNDA were significant departures from agency policy, lacked any reasonable basis in fact based on the record and violated the APA. *Tummino II*, at *18-36, 51-52. The most significant departure was the unprecedented intervention of the HHS Secretary, Defendant Sebelius, in overruling the FDA in an area which Congress has entrusted primarily to the FDA and which fell within the scope of the authority that the Secretary expressly delegated to the Commissioner. *Tummino II*, at *21, (citations omitted). Similar to the government's actions in *Tummino I* where the political interference in decision making by the FDA was improperly influenced by the Bush White House, in taking this action, "[t]he motivation for the Secretary's action was obviously political." *Tummino II*, at *21-22. "[T]he secretary's decision to retain behind-the-counter status for Plan B One-Step was based on politics rather than science. It cannot be based on issues of safety, since a 12 year-old can purchase a lethal dose of acetaminophen in any pharmacy for about $11, no questions asked. [] Any objective review makes it clear that Plan B is more dangerous to politicians than to adolescent girls." *Tummino II*, at *23.

The Secretary's observations about supposed "cognitive and behavioral differences" between "older adolescent girls and the youngest girls of reproductive age" were also determined by the Court to lack reasonable factual basis and violate the APA. *Tummino II*, at *25-29. In the FDA's scientific staff review of the *first SNDA for Plan B*, these observations were refuted as beyond the scope of the FDA's review and were "more applicable to the ability of adolescents to make reasoned decisions about engaging in sexual intercourse, not their ability to understand

how to use Plan B safely and effectively as an emergency contraceptive[.]" *Tummino II*, at *26 (emphasis added). The Secretary's observations also had no factual basis in statistics showing that 12% of the total U.S. population over age 16 are deemed "below basic" document literacy (for prescription labels), yet the Secretary has never required data to conclusively establish that 100% of potential users of a drug can understand the label or precluded over-the-counter sale of drugs for that reason. *Tummino II*, at *29. The Court also noted the Secretary's failure to articulate or define any harm that would result from over-the-counter use of levonorgestrel-based contraceptives by this population. Unlike other over-the-counter drugs which can be readily purchased by teens and have very dangerous or even life threatening effects or known abuses such as acetaminophen or dextromethorphan, levonorgestrel-based contraceptives would be among the safest drugs approved for over-the-counter sale for the pediatric population. *Tummino II*, at *30-33. Finally, in highlighting the arbitrariness of the Secretary's action, the Court also noted that the Secretary never questioned the adequacy of the evidence regarding the ability of older adolescents between the ages of 13 and 16 to understand Plan B One-Step's label and use it correctly, nor did the government ever explain its position why Plan B One-Step should not be made available to them. *Tummino II*, at *34-37.

In perhaps the "most significant unexplained deviation from FDA practice ordered by the Secretary" which lacked a reasonable factual or legal basis, the FDA failed to extrapolate studies and data concerning emergency contraception from one age group to support approval in another age group contrary to agency policy, practice and the APA. *Tummino II*, at *37-48. Defendants' motion for summary judgment did "not provide any evidence to contradict a record which shows that the FDA has engaged in extrapolation at the very least from older to older adolescents with respect to the issues of actual use and label comprehension." *Tummino II*, at *47-48.

The Court's opinion was very specific and detailed in reviewing the unreasonableness of the government's pre-litigation and litigation positions in this area in which they claimed that extrapolation was not the policy of the agency. (ECF No. 71.) The Court's findings included, for example: (1) the government's failure to extrapolate the data available through studies on emergency contraception consistent with FDA policy after telling the Plan B sponsor that the results from trial in the adult population could be extrapolated to the postmenarcheal population; (2) the FDA's own advisory committee of outside experts voted overwhelmingly 23-4 in favor of over-the-counter status in 2003 and 27-1 that the actual use study data by the Plan B sponsor could be generalized to the overall population of potential non-prescription users of Plan B (i.e., data from older groups could be extrapolated to younger ones); (3) in reviewing the actual use data presented by the Plan B sponsor concerning adolescents enrolled in an actual use study, FDA scientific staff confirmed "the Agency has a long history of extrapolating findings from clinical trial in older patients to adolescents in both prescription and nonprescription approvals," a practice incorporated into the Pediatric Research and Equity Act; (4) minutes from an internal FDA meeting in May 2004 commenting that the FDA's failure "to extrapolate adolescent safety and effectiveness data for under 14 year old females is not consistent with how [the Center for Drug Evaluation and Research] handles approval and distribution of prescription oral contraceptives"; and (5) that the FDA did engage in extrapolation in considering the Plan B One-Step SNDA.[6] *Id.*, at *37-48.

[6] In addition, the Court found that Defendants' own summary judgment motion identified a significant related departure from agency practice in this area: when the FDA has declined to extrapolate because of safety concerns, it used labeling to indicate that the drug was not to be made available to children. *Tummino II*, at *48-51. The government cited examples where FDA allowed drugs to be sold over-the-counter that it *did not consider safe* for use in the pediatric population. *Id.* (emphasis in original). "FDA's willingness to rely on labeling to make these drugs available for sale over-the-counter without any age or point-of-sale restrictions, even though they are unsafe for unsupervised use by young adolescents, stands in stark contrast to its refusal to make equally available concededly safe and time-sensitive levonorgestrel-based emergency contraceptives." *Id.*, at *51.

The point-of-sale restriction on over-the-counter sale of levonorgestrel-based emergency contraception was also determined by the Court to have no reasonable factual or legal basis. *Id.*, at *51-63. The FDA "did not have the authority to mandate point-of-sale restrictions on drugs approved for nonprescription sale that it found to be safe and effective for all women of childbearing age[,]" and "even if it had such authority, it clearly deviated from the policy here." *Id.*, at *62. Defendants' arguments were rejected as unreasonable because they were contradicted by the factual record and lacked any legal basis. *See id.*, at *54-56 (noting record evidence showing that point-of-sale restrictions not adopted voluntarily by Plan B sponsor).

The Court found that the FDA's decision denying the Citizen Petition was "compelled" and "inevitable" based on the reasoning and order by the Secretary to reject the Plan B One-Step. *Id.*, at *64-87. For example, "[t]he FDA spent a considerable portion of the Citizen Petition Denial Letter discussing the Plan B One-Step SNDA and the various studies submitted in its support. More significantly, the very reason the FDA claimed it denied the Citizen Petition was the lack of age-specific data, as compared to that submitted with the Plan B One-Step SNDA." *Id.*, at *64. However, even if Plaintiffs had been able to provide such data, the FDA still would have been forced to deny their petition on the grounds articulated by the Secretary. *Id.*, at *75. Therefore, the Court found that "the suggestion that the plaintiffs need to provide 'additional data' comparable to that in the Plan B One-Step application 'to support a switch of Plan B for women young than 17 years of age' is simply a complete pretext – another example of the bad faith that has permeated the FDA's consideration of the Citizen Petition from beginning to end." *Id.*

The Court also noted the unsound factual reasoning of the Citizen Petition denial letter, including the lack of any affidavit or other support on Defendants' motion for summary judgment to explain its flawed reasoning. *Id.*, at *76. The FDA failed to offer any explanation, much less factual or legal support, as to why Plan B should be treated differently from other drugs so as to require numerous deviations from agency policies and practices, including failing to acknowledge or explain the FDA's own policy and precedent of approving drugs for over-the-counter sale even where there is a real concern about their safety. *Id.*, at *76-77. The FDA also failed to justify the creation and maintenance of a new and unprecedented behind-the-counter point-of-sale marketing program to pharmacies and health clinics (for a drug where safety and efficacy is unquestioned and poses a lesser risk to health than many other over-the-counter drugs). *Id*.

While "these unexplained departures from precedent alone render the denial arbitrary, capricious and unreasonable, they are not the only reasons" on which the Court reversed the denial of the Citizen Petition. *Id.*, at *77. The record showed that FDA's claim that no new data had been submitted by Plaintiffs or any other sources to meet the requirements for the FDA to remove the prescription requirements for Plan B for women under age 17 since the 2009 remand was untrue. *Id.*, at *77. The FDA had data from at least two sources: (1) the actual use and label comprehension studies submitted by the Plan B sponsor in support of its SNDA; and (2) the FDA conceded that in its independent literature review, it considered the label comprehension study conducted by Dr. Miriam Cremer which indicated that adolescents understood the concepts necessary for safe and effective use of emergency contraception as well as adults do. *Id.*, at *77-82.

Defendants' position, during and prior to the litigation, that the Plan B One-Step actual use study (or any data or studies for Plan B One-Step) could not be used to support over-the-counter access to Plan because Plan B involves two pills taken 12 hours apart instead of one pill was determined to be unreasonable based on the agency's own approval of Plan B One-Step which demonstrated the agency's "recognition that there would be no adverse consequences or decrease in effectiveness if the two pills were taken at the same time or less than 12 hours apart." *Id.*, at *82-84. As the Court found, the regime the Defendants had in place affected the "most significant factor in terms of effectiveness of the product because it increases the delay between sexual intercourse and the first dose (the only dose in the case of Plan B One-Step)" which "scientific evidence in the record establishes" as "[t]he most important factor concerning timing of dosing and effectiveness" and that "[i]t is [] unlikely that the effectiveness of Plan B will be reduced if the second tablet is taken 6 to 18 hours, instead of exactly 12 hours, after the first dose." *Id.*, at *84 (quoting Medical Officer's Safety Rev. of SNDA at T-30799 (March 25, 2004), Case No. 05-cv-366, ECF No. 235-3; Raymond Decl. ¶ 36).

Moreover, the two-pill actual use study submitted with the original Plan B SNDA demonstrated that there was "excellent compliance" with the label dosing regimen among subjects under 18 years of age. *Id.*, at *85. These results were confirmed by an FDA scientific staff review. *Id.*, at *85-86. The actual use study also did not support Defendants' position that the intervention by a health care provider (such as pharmacist or doctor) impacts the timing of the second dose. *Tummino II*, at *86, n.11 (citing Deputy Div. Dir. Summ. Rev. at T-30840-41, Case No. 05-cv-366, ECF No. 235-4).

The Court's ruling on the government's action on the denial of the Citizen Petition made clear that "despite the FDA's fanciful effort to make it appear that it undertook an independent review of the Citizen Petition[,]" the denial letter, "which came five days after the denial of the Plan B One-Step SNDA, was clearly prompted by the Secretary's action[.]" *Id.*, at *86.

> Because the Secretary's action was politically motivated, scientifically unjustified, and contrary to agency precedent, it cannot provide a basis to sustain the denial of the Citizen Petition. [E]ven considering the Citizen Petition Denial Letter in isolation, the agency's decision cannot withstand any degree of scrutiny, not only because of its unexplained failure to follow the FDA policies [] but also because of its disregard for the scientific evidence that the FDA had before it.

*Id.*, at *86-87.

Finding that Defendants' positions – prior to and during the litigation – were unreasonable as a matter of fact and law, the Court reversed the FDA's decision denying the Citizen Petition and remanded the case to the FDA with the instruction to "grant the Citizen Petition and make levonorgestrel-based emergency contraceptives available without a prescription and without point-of sale or age restrictions within thirty days." *Id.*, at *102.

The Court noted that "if the FDA actually believes there is any difference between the one- and two-pill products, it may limit its over-the-counter approval to the one-pill product. *Id*. The government ultimately agreed to remove all age restrictions on Plan B One-Step, following with the Court's Order, but only after engendering additional litigation by filing an appeal of the Court's decision in *Tummino II* and further restricting access to emergency contraception to only allowing access to the most expensive product, Plan B One-Step, to those 15 and older who could show government issued ID at stores with on-site pharmacies and ending prescription access for anyone younger, and keeping all other products behind-the-counter subject to the same restrictions at issue in the litigation. *Tummino III*, at *11-12, 19.

In response to their announcement of intent to dismiss their appeal and "comply" with the Court's Order by making Plan B One-Step available over-the-counter without age or point-of-sale restriction (only after unsuccessful requests for stays of this Court's Order before this Court and the U.S. Court of Appeals for the Second Circuit), Plaintiffs' filed objections to Defendants' continued refusal to approve all levonorgestrel-based emergency contraceptives over-the-counter based on this Court's decision in *Tummino II*, including two-pill products. (ECF Nos. 103, 105.) In reviewing Defendants' plan to comply with the Court's Order, the Court re-iterated that Defendants were ordered "to make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale restrictions" within thirty days. (ECF No. 106 at 3.) Granting an SNDA for Plan B One-Step "will have the effect of making it available without a prescription or point-of-sale or age restrictions," since "Plan B One-Step is one such emergency contraceptive," but the Court had not "order[ed] the defendants to make the brand-name Plan B One-Step available over-the-counter without age or point-of-sale restrictions" as a matter of jurisdiction. *Id.* The Court acknowledged concerns expressed by Plaintiffs that a grant of marketing exclusivity to Teva was not warranted and would "only burden poor women." *Id*. at 6. The Court also noted that [i]t is because of the extraordinary efforts by the plaintiffs in pursuing their Citizen Petition that Teva is able to seek approval of an SNDA" and "such approval, if given, will be nothing more than a reward to Teva for playing along with the defendants' efforts to maintain their legally and scientifically unjustified restrictions on the marketing of levonorgestrel-based emergency contraceptives." *Id.*

## II. The Amount of Fees Sought is Reasonable

As discussed below in Section II.B., certain members of Plaintiffs' legal team are entitled to enhanced hourly rates above the EAJA statutory rate based on the application of a "special

factor." Accordingly, the lodestar calculations herein reflect these calculations. *See* 28 U.S.C. § 2412(d)(2)(a)(ii). Plaintiffs have not sought an across the board enhancement for all counsel, but have carefully applied the applicable factors to seek enhancement where warranted as discussed in Section II.B.1.a.b., *infra*.

Following the determination of an entitlement to EAJA fees, the court determines what fee is reasonable by a calculation known as the lodestar: the number of hours reasonably expended on the litigation multiplied by a reasonable hourly rate. *Hensley*, 461 U.S. at 433. Plaintiffs' lodestar calculations are included below and supported by the declarations and accompanying exhibits for each attorney and paralegal listed below filed contemporaneously herewith.[7]

Plaintiffs seek fees totaling $743,862.75 for work before the District and Appellate Courts as discussed below. The chart below provides the lodestar calculations for the counsel seeking an enhanced hourly rate based on application of a special factor and for other counsel based on an EAJA statutory rate applying a cost of living increase as explained in Section II.B.1.c., *infra*. (The calculation for all counsel using the "bad "faith" application of market rates in the EAJA, 28 U.S.C. § 2412(b), is in Section II.B.2, *infra*.)

| **Attorney** | **Law School Graduation** | **Requested Rate** | **Hours** | **Total** |
|---|---|---|---|---|
| Janet Crepps | 1983 | $650 | 117.1 | $76,115 |
| Suzanne Novak | 1997 | $560 | 449.3 | $251,608 |
| Andrea Costello | 1998 | $560 | 305.2 (PCJF)<br>51.3 (FILS) | $170,912 (PCJF)<br>$28,728 (FILS) |
| Kirsten Clanton | 2005 | $450 | 131.4 | $59,130 |
| | | | | |

[7] The application of the "special factor" above the EAJA hourly rate for counsel is explained in Section II.B., *infra*.

| | | | | |
|---|---|---|---|---|
| Natalie Maxwell | 2005 | $450 | 26.6 | $11,970 |
| Mara Verheyden - Hilliard | | EAJA with cost of living | 43.2 | $8,638.75 |
| Carl Messineo | | EAJA with cost of living | 17.8 | $3,560.00 |
| Fried Frank Attorneys and Paralegal | | EAJA with cost of living | 747.1 | $131,698.00[8] |
| Candice Kalis | Paralegal and 2012 Law School Graduate (PCJF) | $90 | 16.7 | $1,503.00 |
| | | | **LODESTAR TOTAL:** | **$743,862.75** |

### A. The Number of Hours Claimed is Reasonable

"Where a plaintiff has obtained excellent results, his attorney should recover a fully compensatory fee. Normally this will encompass all hours reasonably expended in this litigation…" *Hensley*, 461 U.S. at 435. Plaintiffs' counsel achieved excellent results – the Court found that Defendants had violated the APA and had arbitrarily, capriciously and unreasonably denied the Citizen Petition based on actions and decisions that were "politically motivated, scientifically unjustified, and contrary to agency precedent." *Tummino II*, at *86. Accordingly, the Court remanded with directions that Defendants, "grant the Citizen Petition and make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within thirty days." *Id.*, at *102. Plaintiffs were awarded the injunctive relief which they sought and should be compensated for all of the hours claimed.

[8] *See* Declaration of Janice Mac Avoy, ¶ 8 for explanation of calculations of EAJA rates for all Fried Frank counsel and paralegals. As explained therein, Fried Frank has applied a 10% reduction in the number of hours for which they are seeking compensation to account for any additional potential inefficiencies that may have not been accounted for in Ms. Mac Avoy's prior adjustments of the time entries. Id., ¶ 7.

As explained in the declarations of Plaintiffs' counsel, the number of hours for which compensation is sought is reasonable. Declaration of Andrea Costello (Costello Decl.), Ex. A, B, ¶¶ 11, 15; Declaration of Janet Crepps (Crepps Decl.), Ex. A, ¶¶ 2-3; Declaration of Suzanne Novak (Novak Decl.), Ex. A, ¶ 8; Declaration of Kirsten Clanton (Clanton Decl.), Ex. B, ¶¶ 16; Declaration of Natalie Maxwell (Maxwell Decl.), Ex. B, ¶ 11, 17; Declaration of Mara Verheyden-Hilliard (Verheyden-Hilliard Decl.), Ex. A, ¶¶ 12-14; Declaration of Carl Messineo (Messineo Decl.), Ex. A, ¶¶ 12-13; Declaration of Janice Mac Avoy (Mac Avoy Decl.), Ex. A, ¶¶ 3-4, 6-7; Declaration of Candice Kalis (Kalis Decl.), Ex. A. The attorneys and other staff carefully documented the work they performed by maintaining contemporaneous time records and detailed the time spent broken down by date and activity. *Id.* Plaintiffs' counsel also exercised substantial billing discretion in the submission of hours and costs, including the exclusion of *de minimis* phone calls, meetings, consultations and emails, as well as not billing for travel costs for out of state counsel and other no billed costs.

Throughout this litigation, counsel divided responsibilities for work in the case to avoid duplication of effort and have also exercised billing judgment to eliminate unnecessary or duplicative hours. *Id.* Plaintiffs are also not seeking compensation for approximately 200 hours spent by several legal fellow attorneys, law students, or legal assistants employed by the Center for Reproductive Rights who, over the course of the litigation, provided hours of assistance with tasks which were necessary for this litigation. Crepps Decl., ¶ 13. The relevant time period for all of Plaintiffs' counsels' billing records commence after this Court's decision in *Tummino I*.

### B. The Hourly Rate Claimed is Reasonable

#### 1. Compensation is Warranted Above the EAJA Statutory Hourly Rate for Attorneys Whose Special Expertise and Experience was Needed in the Litigation

The EAJA generally authorizes fees at $125 per hour adjusted for inflation, however, a court may award fees at a higher rate where "a special factor, such as the limited availability of qualified attorneys for the proceedings involved, justifies a higher fee." 28 U.S.C. § 2412(d)(2)(a)(ii). "[L]imited availability of qualified attorneys for the proceedings involved" refers to "attorneys having some distinctive knowledge or specialized skill needful for the litigation in question – as opposed to an extraordinary level of general lawyerly knowledge and ability useful in all litigation." *Pierce*, 487 U.S. at 572. Examples would be an "identifiable practice specialty such as patent law, or knowledge of foreign law or language." *Id.* Thus, enhanced hourly rates based on this "special factor" may be awarded where the attorney has a distinctive knowledge or specialized skill, such knowledge and skills were necessary for the litigation and can only be obtained at rates in excess of the statutory cap. *Id.*; *David v. Sullivan*, 777 F. Supp. 212, 220-21 (E.D.N.Y. 1991).

**a. Plaintiffs' Counsel Have Distinctive Knowledge or Skill Which Was Required for This Litigation**

Awards under the EAJA are awarded as matter of practice from courts applying this special factor.[9] Moreover, an award based on the special factor of the limited availability of qualified attorneys with knowledge or specialized skill is appropriate when the attorneys have extensive and unique knowledge of the procedural history and legal issues in a matter, where for example, they have previously litigated a virtually identical case. *See*, *e.g.*, *David*, 777 F. Supp. at 221; *see also* Declaration of Carol A. Sobel (Sobel Decl.), ¶11. These attorneys have direct expertise with the complex statutory scheme at issue, knowledge of the agency involved, and an

[9] *See, e.g.*, *Martin v. Secretary of the Army*, 463 F. Supp. 2d, 287, 293 (collecting cases where District Courts have applied fee enhancement in cases for lawyers with specialized expertise), citing *Raines v. Shalala*, 44 F.3d 1355, 1361 (7th Cir. 1995); *Pirus v. Bowen*, 869 F.2d 536 (9th Cir. 1989); *Nadarajah v. Holder*, 569 F.3d 906 (9th Cir. 2009); *Jean v. Nelson*, 863 F.2d 759 (11th Cir. 1988); *Nat'l Labor Relations Bd. v. Pueblo of San Juan*, 305 F. Supp. 2d 1229 (D.N.M. 2003); *Conn. State Dep't of Soc. Servs. v. Thompson*, 289 F. Supp. 2d 198 (D. Conn. 2003).

understanding of the needs of the population involved. In fact, such attorneys may be the "only [counsel that]… showed the interest and capacity necessary to investigate and obtain relief," and were "uniquely suited to handle the post-judgment proceedings in this action efficiently in light of the highly specialized legal and factual knowledge necessary to undertake them." *See, e.g.*, *David*, 777 F. Supp. at 220-21; *see also Pirus v. Bowen*, 869 F.2d 536 (9th Cir. 1989) (fees in excess of EAJA cap awarded to attorneys who had represented plaintiff class in class action and had previously taken similar class action to Supreme Court). These factors are present here.

Through their experience litigating the unprecedented complex legal and factual issues in *Tummino I*, Plaintiffs' counsel[10] has distinctive knowledge or specialized skill needed for this litigation which afforded them a unique familiarity and expertise that no other attorneys in the country possessed concerning the FDA's administrative process related to the over-the-counter status of emergency contraception. *See* Declaration of Jennifer Dalven in Support of Plaintiffs' Motion for Attorneys' Fees, ¶¶ 5-11; Sobel Decl., ¶¶ 11-14; Declaration of Peter P. Sleasman (Sleasman Decl.), ¶¶ 3-8. This knowledge and specialized skill was critical to Plaintiffs' success here.

The nuanced understanding of the FDA's long and complicated over-the-counter administrative process concerning emergency contraception possessed by Plaintiffs' counsel in this litigation is knowledge or skill that cannot be obtained by a competent practicing attorney through routine research or legal experience and is a "distinctive or specialized skill needful for the litigation in question – as opposed to an extraordinary level of the general lawyerly knowledge and ability useful in all litigation." *Pierce*, 487 U.S. at 572; *see also Pirus*, 869 F.2d at 536. This experience and skill could *only* be obtained by litigating the factual and legal

[10] As noted previously, only certain of Plaintiffs' counsel are seeking an enhanced rate under the special factors, and thus, are generally referred to here.

complexities which were based on the government's 12 year abuse of the administrative process through arbitrary and capricious decision-making concerning emergency contraception for improper political purpose. Counsels' experience in litigating the highly unusual – and perhaps unprecedented – legal challenge under the APA in *Tummino I* was "an experience which afforded them the unique familiarity with its procedural history and the knowledge of legal issues which was essential to the post-judgment proceedings." *David*, 777 F.Supp. at 221. This specialized knowledge and experience made Plaintiffs' counsel the only advocates uniquely suited to handle the post-judgment proceedings in the action efficiently in light of the highly-specialized legal and factual knowledge necessary to undertake it. *Id.* The Court acknowledged the specialized experience and knowledge possessed by Plaintiffs' counsel in litigating *Tummino II* when it noted that it was "only because of the extraordinary efforts by the plaintiffs in pursuing their Citizen Petition that Teva is able to seek approval of an SNDA that will permit it to market its product with no point-of-sale or age restrictions" and that "plaintiffs… are responsible for the outcome of this case." (ECF No. 106 at 6.)

As the Court noted at the hearing on Defendants' motion for a stay of the April 5, 2013, Order, this case was a highly unusual and unique legal challenge under the APA. (Tr. of May 7, 2013, Hearing, 75:23-25)("[] I'm going to write an opinion in this case. I'm not deciding this today. The irony of this all is that I would be allowing what the FDA wanted to do and an exercise of its best scientific and expertise, to be done. I mean this is got to be one of the most unusual administrative law cases I've ever seen[.]") This case is precisely the type of non-routine complex litigation which is litigated by attorneys with specialized knowledge and experience that is entitled to an increased fee award under EAJA. *See, e.g., Lagana v. Sec. of Health and Human Services*, 1992 U.S. Dist. Lexis 10424, *9 (E.D.N.Y. July 13, 1992); *see also* Dalven Decl. ¶ 8.

In addition to the specialized skills and knowledge explained above, as summarized below and explained more fully in supporting Declarations, Plaintiffs' counsel possess distinctive knowledge and expertise in complex civil rights litigation, advocacy for women's reproductive healthcare, an understanding of healthcare needs of the population whose rights were at stake in this case and a long and close relationship with the population and client base represented in this case. *See* Crepps Decl., ¶¶ 4-7; Costello Decl., ¶¶ 4-6, 14, 16-20; Novak Decl., ¶¶ 1, 4-6, 8; Clanton Decl. ¶¶ 6-13, 17-27; Maxwell Decl., ¶¶ 5-6, 18-24; *see also* Sobel Decl., ¶¶ 6-11; Dalven Decl., ¶ 6. This level of expertise was needed in this litigation and is not available at the EAJA statutory rate, as explained in the supporting Declarations. *Id.*

Janet Crepps, lead counsel for CRR, is one of the most experienced reproductive rights litigators in the country. Crepps Decl., ¶ 7. Since 1993, she has worked continuously at CRR (formerly the Center for Reproductive Law & Policy), beginning as a staff attorney dedicated to state legislative analysis and advocacy, including extensive work on insurance coverage for contraceptives. *Id.* ¶ 5. In 1995, Ms. Crepps began working on the Center's litigation. *Id.* In 1998, she was the Acting Director of the Center's Washington, D.C. office, responsible for developing the Center's positions on federal legislation and for lobbying on Capitol Hill. *Id.* From 1998 until now, Ms. Crepps's work has focused primarily on the Center's litigation. *Id.* During that time, she has worked on complex reproductive rights cases at all levels of the state and federal court systems. *Id.*, ¶¶ 5-6. Ms. Crepps brings specialized experience and knowledge to this litigation having litigated cases involving the impact of abortion restrictions on low-income and rural women, and challenges to parental notification and consent requirements for young women seeking abortion. *Id.*, ¶ 6. Through this work, Ms. Crepps brought specialized knowledge of how restrictions on access to reproductive health care affect vulnerable

populations, such as those women most affected by the restrictions on access to emergency contraception. In addition, Ms. Crepps endeavors to keep up with the social science literature related to access to reproductive health care, and had reviewed many of the studies on emergency contraception prior to her direct involvement in the litigation. Ms. Crepps is a recognized legal expert in the field of reproductive rights and frequently presents at conferences, including meetings of the National Abortion Federation, the Abortion Care Network, and the American Public Health Association. *Id.*, ¶ 7. Ms. Crepps first entered an appearance in the original litigation challenging the Defendants' refusal to grant the Citizen Petition on April 7, 2008. *Id.*, ¶ 9. Having been employed at CRR at the time of the filing of the emergency petition, she was familiar with the issues. Even prior to entering her appearance, she followed the case closely, reading the pleadings and regularly consulting with CRR attorneys on strategy and other issues. *Id*. Her extensive knowledge of the case assisted her in effectively litigating the issues when she became actively involved. Beginning in 2010, Ms. Crepps worked closely with Suzanne Novak and reviewed virtually all significant pleadings from the development of the motion for contempt through the summary judgment filings related to the supplemental complaint. *Id*. Beginning in October 2012, when Ms. Novak left CRR, Ms. Crepps became lead counsel on this case. *Id.* In that capacity, Ms. Crepps drafted pleadings, participated in and approved of all strategic decisions in this case, participated in telephonic conferences with co-counsel, worked closely with experts, reviewed and approved of all submissions to the Court, managed the work of CRR staff, and took the lead at oral argument on the government's motion to stay the district court's April 5, 2013, judgment pending appeal. *Id*.

Suzanne Novak, former lead counsel for CRR,[11] has extensive experience litigating reproductive rights and complex constitutional cases in both state and federal courts. Novak Decl., ¶ 6. She graduated *cum laude* with a J.D. from the New York University School of Law in 1997. *Id.*, ¶ 4. After clerking for the Honorable Stephen M McNamee in the federal district court in Arizona, Ms. Novak spent two years at CRR as a Blackmun Fellow before working as an associate at Arnold & Porter LLP. *Id.*, ¶ 5. She returned to CRR as a staff attorney and then went on to serve as the Deputy Director of the Democracy Program at the Brennan Center. *Id.* In September 2007, Ms. Novak left the Brennan Center and came back to CRR as a consulting attorney. *Id.* From August 2008 until October 2012, Ms. Novak was a Senior Staff Attorney in CRR's U.S. Legal Program and litigated numerous complex reproductive rights cases in the federal and state courts. *Id.* Among the cases that Ms. Novak has litigated are *Planned Parenthood v. State*, a challenge to an Alaska law requiring minors to obtain parental consent prior to abortion. *Id.*, ¶ 6. Through this case and others, Ms. Novak gained specialized knowledge about access to reproductive health care for minors. As lead counsel in a challenge to restrictions on medication abortion in North Dakota, Ms. Novak built a record documenting the impact of restrictions on women in a rural state with limited reproductive health care services. Ms. Novak was lead counsel on this case from the time the Court entered summary judgment in favor of Plaintiffs' in March 2009 until her departure from the Center in October 2012. *Id.*, ¶ 8. During that time, she did much of the thinking regarding strategy for the case, consulted with co-counsel, and took primary responsibility for implementing decisions. *Id.* She was responsible for all written documents, many of which she drafted, and participated in several court

[11] Ms. Novak served as lead counsel for the Center for Reproductive Rights in this case until October 30, 2012, when she was no longer employed at CRR. *See* ECF No. 76.

appearances. *Id.* Ms. Novak was also the main point person for contact with outside consultants, declarants/experts witnesses, and opposing counsel. *Id.*.

Andrea Costello, lead counsel for the National Women's Liberation (NWL) individual Plaintiffs and Anaya Kelly, has extensive experience as a national civil rights litigator for the past 15 years serving as lead counsel or co-counsel in cases brought in federal District and Appellate Courts, in New York, Florida and the District of Columbia. *See* Costello Decl., ¶¶ 4-8; see also Sobel Decl., ¶¶13-14. Ms. Costello graduated from the City University School of Law in Queens College in 1998. *Id*., ¶ 3. Ms. Costello brings specialized experience and knowledge to this litigation having served as lead counsel for the NWL Plaintiffs[12] since *Tummino I* was originally filed in 2005 and is the only attorney who has been involved, and remained involved, in this matter since its inception. *Id.*, ¶ 13. As a result, she has extensive knowledge of the factual record and legal issues in this case, the procedural history in *Tummino I* and the FDA's consideration of emergency contraception from prescription only to an over-the-counter drug – all of which played an important role in Plaintiffs' successful efforts in *Tummino II*. *Id.*, ¶¶ 13-14, 16, 19. She has served as lead counsel in complex civil rights class actions against government agencies in Florida, New York and federally, including, for example, class actions and systemic impact litigation against the New York City Police Department to challenge its unconstitutional stop-and-frisk practices, Florida Agency for Health Care Administration, Florida Department of Health and Florida Department of Juvenile Justice related to the failure to provide health care to persons through state or federal health programs or in state custody. *Id*., ¶¶ 4-6. She has also engaged in policy work in the State of Florida to secure access to needed healthcare services for low-income persons with disabilities and seniors. *Id*., ¶¶ 4-5. As part of

[12] Formerly known as the Morning-After Pill Conspiracy. *See* First Amended Supplemental Complaint (ECF No. 14 at ¶¶ 7-8.)

her litigation and policy work concerning access to healthcare for persons with disabilities and youth in, or at risk for the criminal justice system in Florida, she was recognized as an expert in the state and consulted regularly with attorneys, advocates and the media on these issues based on her experience and specialized knowledge. *Id.*, ¶ 8. She has lectured to legal organizations, public interest organizations, law schools and the public concerning civil rights issues and reproductive rights. *Id.*, ¶ 9.

Ms. Costello has a unique and long-standing relationship with the NWL Plaintiffs and has provided legal representation and assistance to NWL, and its members, including as part of their activities to advocate for unrestricted over-the-counter access to emergency contraception concerning over-the-counter access on emergency contraception which relate to this litigation. *Id.*, ¶¶ 13-14, 17-19. Ms. Costello also provided legal representation to minors in the State of Florida who were seeking a judicial waiver of Florida's law requiring parental notification to obtain an abortion and trained and provided consultation to other attorneys to conduct these hearings. *Id.*, ¶¶ 4, 6.j.. She brought the specialized knowledge and understanding gained from working with adolescents on issues of access to reproductive health to her work in this litigation. In addition to her legal experience, she has been a committed advocate for access to women's reproductive healthcare for 20 years through work in women's rights advocacy organizations, as a member and leader in progressive legal organizations, and as a reproductive health educator prior to her legal career and applied this knowledge in this litigation. *Id.* ¶ 20.

Plaintiffs' counsel, Kirsten Clanton and Natalie Maxwell served as co-counsel for the NWL Plaintiffs (Ms. Clanton also represented Anaya Kelly) and specialize in complex civil rights litigation. Ms. Maxwell graduated from American University, Washington College of Law in 2005. Ms. Clanton graduated from University of Florida, also in 2005. They each have a

level of skill and knowledge that was required in this litigation and is not available at the EAJA statutory rate, as explained in the supporting declarations. *See* Clanton Decl.; Maxwell Decl.; and Sleasman Decl..

Ms. Maxwell was involved in *Tummino I*, experience that was necessary to her representation of the Plaintiffs after remand and during contempt proceedings.[13] Maxwell Decl. ¶ 13. Ms. Maxwell is a recognized leader in public interest law. She has planned and trained at statewide trainings for legal services lawyers on litigation. Maxwell Decl. ¶ 7, Ex. A. She has presented on issues regarding reproductive rights of minors. *Id*. She served as a Committee Member of the National Housing Law Project's, HUD Housing Programs: Tenant Rights' Manual, the most comprehensive resource available on this topic. *Id*. She edited and revised sections on tenant participation, and has also presented on First Amendment rights of public housing tenants. *Id*.

Ms. Clanton substituted for Ms. Maxwell on Plaintiffs' team after Ms. Maxwell's departure from Southern Legal Counsel (SLC). Clanton Decl., ¶ 19. Although Ms. Clanton was not attorney of record until March 2012, she had knowledge of the facts and legal issues involved with *Tummino I* when she began working at SLC in 2007 because SLC attorneys meet regularly to discuss cases and Ms. Clanton also kept apprised of the case by reading court filings to be able to provide opinions about case strategy and other legal issues at the attorney meetings. Clanton Decl., ¶¶ 19-20, 25.

Ms. Clanton's skill and experience in complex constitutional litigation, particularly in cases involving intersections of statutory, administrative and constitutional law, was important to this litigation. *Id.*, ¶¶ 5-26, 24, 26. Ms. Clanton is a recognized leader in public interest law.

[13] Ms. Maxwell served as co-counsel for the NWL Plaintiffs in this case until she left employment at Southern Legal Counsel. *See* Maxwell Decl.

She was the Chair of the Public Interest Law Section of The Florida Bar from 2011-2012. *Id.*, ¶ 9. She is invited to speak regularly at conferences on civil rights, particularly constitutional issues, and was invited by the Sargent Shriver National Center on Poverty Law to be a trainer for their Affirmative Litigation Training, a nationally recognized training on federal court litigation. *Id.*, ¶¶ 10-11. She also was invited to be a reviewer for the Center's 2014 update of their Federal Practice Manual for Legal Aid Attorneys, a popular resource that covers all stages of federal litigation. *Id.*, ¶ 12.

Ms. Clanton and Ms. Maxwell have provided legal representation to minors in the state of Florida who seek a judicial waiver of Florida's law requiring parental notification of termination of pregnancy. Clanton Decl., ¶ 6; Maxwell Decl., ¶¶ 5-6. This representation has involved litigation over the constitutional right to privacy of minors in these proceedings. *Id.* Ms. Clanton and Ms. Maxwell have provided technical assistance and training to other lawyers in these cases, and also have received regular referrals from the courts and clinics around North Florida to provide advice and legal counseling to minors regarding their reproductive rights. *Id.*

**b. Attorneys with Counsels' Knowledge and Skill are not Available at the Statutory EAJA Rates**

Where an attorney is entitled to a special factor increase of the statutory fee rate under EAJA, the court awards a reasonable fee based on that attorney's prevailing market rate. *See, e.g., David*, 777 F. Supp. at 220-21; *SEC v. Wilson*, [14] 2009 U.S. Dist. LEXIS 66245, at *31-35; *Martin*, 463 F. Supp. 2d at 293. Plaintiffs are seeking reimbursement for time expended at the hourly rates of $650 for Janet Crepps, $560 for Suzanne Novak, $560 for Andrea Costello, $450 for Kirsten Clanton and $450 for Natalie Maxwell. (All other counsel are seeking reimbursement

[14] In *SEC v. Wilson*, 2009 U.S. Dist. LEXIS 66245, at * 34 (D. Conn. July 31, 2009), similar to here, no special factor was sought for a private firm which also provided services for the prevailing party. The court used the cost of living adjustment for the EAJA statutory rate in calculating the fees for which plaintiff was entitled for the services of the firm.

at the EAJA hourly rate adjusted for inflation, or, in the alternative, fees at the prevailing market rate based on the "bad faith" exception. *See* Section II.B.2., *infra*.) As explained below, these rates are reasonable for the Eastern District of New York.

The process of determining the appropriate hourly rate requires weighing a number of factors. The Supreme Court has declared that the reasonable hourly rate to be applied in awarding fees under statutory fee provisions is the "prevailing market rate," that is, the rate that lawyers of similar skill, reputation and experience would charge in the legal market of that geographic area. *Blum v. Stenson*, 465 U.S. 886, 895-96, n.11 (1984). A court must initially determine what lawyers of comparable skill and experience handling other complex litigation charge their private clients, as "the rates charged in private representations may afford relevant comparisons." *Id.* at 895, n.11.

Other factors considered by the court in addition to the prevailing market rates, include: (1) the time and labor required; (2) the novelty and difficulty of the questions; (3) the skill required to perform the legal service properly; (4) the preclusion of employment by the attorney due to acceptance of the case; (5) the attorney's customary hourly rate; (6) whether the fee is fixed or contingent; (7) the time limitations imposed by the client or the circumstances; (8) the amount involved in the case and the results obtained; (9) the experience, reputation, and ability of the attorneys; (10) the "undesirability" of the case; (11) the nature and length of the professional relationship with the client; and (12) awards in similar cases. *See U.S. and Vulcan Society v. City of New York* ("*Vulcan Society*"), 2013 U.S. Dist. Lexis 125461, *25-28 (E.D.N.Y. Aug. 30, 2013), citing *Johnson v. Georgia Highway Exp., Inc.*, 488 F.2d 714, 717-19 (5th Cir. 1974) (awarding higher than average rates for EDNY where *Johnson* factors indicate case is "exceptional" requiring extraordinary effort and skill, long-running litigation which involved

numerous complex issues and required work by many attorneys, attorneys had exceptional qualifications, obtained significant equitable relief and plaintiffs faced some "unique and significant obstacles").

For Plaintiffs' counsel with the specialized knowledge needed in this litigation which is not available at the EAJA statutory rate, as explained above, Plaintiffs have used the market rate data based on billing rates utilized by attorneys in the Eastern District of New York with comparable experience, skill, knowledge and qualifications based on precedent from this jurisdiction and the Valeo Attorney Hourly Rates Database. *See* E.D.N.Y. attorney fee award case citations, *infra*; *see also* Declaration of Chuck Chandler of Valeo Partners LLC (Chandler Decl.), Ex. A (for attorney graduating in 1983 establishing mean rate of $932 and median rate of $950; for attorney graduating in 1997 establishing mean rate of $810 and median rate of $835); for attorney graduating in 1998 establishing mean rate of $862 and median rate of $867; for attorneys graduating in 2005 establishing mean rate of $666 and median rate of $700); Mac Avoy Decl., ¶¶ 9-13. Plaintiffs have set counsels' market rates at or below the actual market rates for attorneys with comparable experience. *Id.* They also establish that the rates Plaintiffs counsel are seeking are at or below the prevailing market rates at which attorney with such specialized expertise are available. *See* Mac Avoy Decl., ¶¶ 9-13; Chandler Decl., Ex. A.

Precedent in the Eastern District establishes the reasonableness of the rates sought by Plaintiffs. Further, "when reviewing caselaw that comments on prevailing market rates, a court must take into account the rapidity with which such rates can rise. Thus, a case decided even as recently as [three years prior] could be out of date as far as the rates are concerned." *See Tokyo Electron Arizona, Inc. v. Discreet Indus. Corp.*, 215 F.R.D. 60, 63 (E.D.N.Y. 2003) (awarding rates in 2003 of $400 per hour for partners in case brought in Suffolk County); *see also, U.S. v.*

*$61,900*, 856 F. Supp. 2d 484, 494 (E.D.N.Y. 2012) (awarding $600/hour for partner, $400 for associate and $150 for paralegal noting that certain "cases, in which Brooklyn lawyers generally specialize, are high-volume practices that bear little semblance to" the case at bar, which was "based on non-repetitive fact patterns and diverse and complex fields of law."); *Rodriguez v. Pressler, LLP*, 2009 U.S. Dist. Lexis 20655 (E.D.N.Y. March 16, 2009) (awarding $450/hour in 2009 to partner with 17 years of experience and $300 to staff attorney with four years experience in FDCPA case).

When complex litigation is brought in the commercial field, hourly rates of more than $600 are awarded. *See In re Visa Check/Mastermoney Antitrust Litigation*, 2009 U.S. Dist. Lexis 100873 (E.D.N.Y. Oct. 15, 2009) (adopting special master's recommendation that lead counsel be awarded requested rates of $250 to $625, issuer's counsel be awarded between $198 and $792, underwriter's counsel be awarded between $220 and $945 and paralegal be awarded $110 to $170). This was three years ago. Since the hourly rates in complex civil rights cases are intended to follow awards in other complex litigation, those decisions should be a model for this case as well.

Paralegal fees are not subject to the EAJA cap and so may be recovered at prevailing market rates. *See* 28 U.S.C. § 2412(d)(2)(A)(ii) ("*attorney fees* shall not be awarded in excess of $125 per hour") (emphasis added); *see also Richlin Sec. Serv. Co. v. Chertoff*, 553 U.S. 571, 590 (2009) ("a prevailing party that satisfies EAJA's other requirements may recover its paralegal fees from the Government at prevailing market rates"). The rates sought by Plaintiffs for paralegal work in this case are reasonable. *U.S. v. $61,900*, 856 F. Supp. 2d at 494 (2012 award of $150 for paralegal); *Kiely v. Astrue*, 2012 U.S. Dist. LEXIS 135784 at *5 (D. Conn. Apr. 2, 2012) (court awarded rate of $100 for paralegal work in EAJA case).

The attorneys involved in this case are at the highest level of their profession and are well deserving of the requested rates. Complete biographies are provided for each attorney in each individual's Declaration. Abbreviated versions of the attorneys' experience are also included (for those seeking reasonable market rates based on the specialized knowledge needed in this litigation which is not available at the EAJA statutory rate). *See* Section II.B.1.a., *supra*.

The *Johnson* factors indicate that this is an exceptional case meriting the prevailing market rates of Plaintiffs' counsel. *Id.* This case was a unique challenge involving complex legal and factual issues and required intensive efforts by the counsel involved who were highly skilled civil rights and reproductive rights litigators highly respected by their peers. Defendants fought any relief in this case every step of the way, including by attempting to preempt a decision by this Court on Plaintiffs' Motion for Contempt, by repeating factual and legal arguments previously rejected by this Court and refusing to comply with this Court's Order by further restricting access to emergency contraception and then filing an appeal which was ultimately voluntarily dismissed.

The case required extensive time and labor. *See* Novak Decl., Ex. A; Crepps Decl., Ex. A; Costello Decl., Exs. A, B; Clanton Decl., B; Maxwell Decl., Ex. B; and Dalven Decl., ¶ 8. Indeed, Defendants' failure to remedy the bad faith that permeated consideration of Plan B during *Tummino I* is the reason Plaintiffs had the difficult task of expending 12 years of litigation efforts to achieve the excellent results here. Not only did counsel have a longstanding relationship with Plaintiffs, the course of this litigation demonstrated that only Plaintiffs had the political will and fortitude to take on the FDA, the Secretary, and two Presidential Administrations in their fight to make emergency contraception available to all women of child-bearing age without age or point-of-sale restrictions. The conduct of Teva in this case

demonstrated that the integrity of the drug approval process as it relates to emergency contraception could not be left in the hands of pharmaceutical companies and their lawyers. The "undesireability" of jeopardizing other business interests and the drug manufacturers' willingness to acquiesce to unjustified and burdensome age and point-of-sale restrictions in exchange for economic gain is the reason Plaintiffs' extensive efforts were required. *See Tummino II*, *55-56; *Tummino III*, ECF No. 98 at 5-10; Tr. of April 27, 2012, 8:16-9:14; *see also* Dalven Decl., ¶ 5.

As this Court stated in its Order approving Defendants' plan to comply with the April 5 Order:

> It is only because of the extraordinary efforts by the plaintiffs in pursuing their Citizen Petition that Teva is able to seek approval of an SNDA that will permit it to market its product with no point-of-sale or age restriction. Such approval, if given, will be nothing more than a reward to Teva for playing along with the defendants' efforts to maintain their legally and scientifically unjustified restrictions on the marketing of levonorgestrel-based emergency contraceptives. It is the plaintiffs, rather than Teva, who are responsible for the outcome of this case, and it is they, and the women who benefitted from their efforts who deserve to be rewarded.

(ECF No. 106 at 6.)

**c. The EAJA Statutory Rate Should be Adjusted for Inflation for Those Counsel Not Seeking at or Below the Prevailing Market Rate**

The EAJA establishes a presumptive maximum fee rate of $125 per hour, but permits the court to apply an increase in the cost of living. *See* 28 U.S.C. § 2412(d)(2)(A)(ii). The statutory fee rate – which was set at $125 per hour in March 1996, has not kept pace with inflation. Accordingly, courts, including the Second Circuit and the Eastern District of New York, have routinely applied a cost of living adjustment for inflation when awarding EAJA fees. *Harris v. Sullivan*, 968 F.2d 263, 265 (2d Cir. 1992) (establishing that the cost of living increase under the

EAJA is properly measured by the Consumer Price Index – Urban (CPI-U), prepared on a monthly basis by the Bureau of Labor Statistics, U.S. Department of Labor). The court must apply a different cost of living adjustment for each year in which hours were billed, rather than a single adjustment to the total hours.

For Plaintiffs' counsel Mara Verheyden-Hilliard, Carl Messineo, and Fried Frank Counsel for whom compensation is sought, the Court should award fees for all work expended at the EAJA statutory hourly rate adjusted for inflation for fees sought in 2012 and 2013. (These amounts are included in the chart above for Plaintiffs' Total Fees, but included here for the Court's reference.) To calculate the cost of living increase for EAJA fees, the hourly rate should be increased by the corresponding Consumer Price Index for each year in which the legal work was performed. *See, e.g., Kerin v. United States Postal Service*, 218 F.3d 185, 193 (2d Cir. 2000).[15] These calculations result in the rates set out as follows:

| **Attorney** | **2012 Rate** | **Hours** | **Total** |
|---|---|---|---|
| Mara Verheyden-Hilliard | $197.50 | 0.5 | $98.75 |
| Fried Frank Attorneys and Paralegal | | 708.6 | $138,631.16[16] |
| | | **2012 TOTAL:** | $138,729.91 |

| **Attorney** | **2013 Rate** | **Hours** | **Total** |
|---|---|---|---|
| Mara Veryheyden- | $200 | 42.7 | $8,540.00 |

[15] The procedure is for each year in which work was performed, the rate should be determined by dividing that year's CPI-U for the Northeast Region by the CPI-U for March 1996 (the date of the amendments to EAJA that set the $125 per hour statutory rate) and the resulting ratio should be multiplied by $125. The CPI-U for August 2013 – the most recent month available – is 249.85, while the CPI-U for March 1996 was 155.7. *See* ftp://ftp.bls.gov/pub/special.requests.cpi/cpiai.txt. Thus, 249.85/155.7 = 1.6 which is multiplied by $125 per hour, resulting in an inflation-adjusted rate of $200 per hour for 2013. For 2012, the calculation is: 246.46/155.7 = 1.58 which is multiplied by $125 per hour, resulting in an inflation-adjusted rate of $197.50 per hour.

[16] *See* n. 8, *supra*. Fried Frank has applied a 10% discount for the 2012-2013 EAJA fees total for its counsel and paralegals that performed work in this litigation. This discount is reflected in the lodestar total, but this chart reflects calculations for actual hours billed.

| | | | |
|---|---|---|---|
| Hilliard | | | |
| Carl Messineo | $200 | 17.8 | $3,560.00 |
| Fried Frank Attorneys and Paralegal | | 38.5 | $7,700.00 |
| | | **2013 TOTAL:** | $19,800.00 |

| | |
|---|---|
| **TOTAL FEES FOR ATTORNEYS WITH COST OF LIVING ADJUSTMENT** | **$158,529.91** |

**2. Compensation is Warranted Above the EAJA Statutory Hourly Rate Based Upon the Application of "Bad Faith" Market Rates in the EAJA**

As an independent and alternative basis, Plaintiffs are entitled to market rates based on the "bad faith" market rates in the EAJA.[17] This provision stands completely apart from those under which the government may be held liable for fees at certain statutory rates unless its position in litigation is substantially justified. *See Wells v. Bowen*, 855 F.2d 37, 46 (2d Cir. 1988). 28 U.S.C. Section 2412(b) provides:

> Unless expressly prohibited by statute, a court may award reasonable fees and expenses of attorneys . . . to the prevailing party in any civil action brought by or against the United States or any agency or any official of the United States acting in his or her official capacity in any court having jurisdiction of such action. The United States shall be liable for such fees and expenses to the same extent that any other party would be liable under the common law or under the terms of any statute which specifically provides for such an award.

An award of attorneys' fees under this exception applies when the losing party's claims were meritless and made for reasons of harassment or delay or for other improper purposes. *Id.* at 46 (citations omitted); *see, e.g.*, *Kerin*, 218 F.3d at 190; *Brown v. Sullivan*, 724 F. Supp. 76 (W.D.N.Y. 1989) (defendant found to have acted in bad faith because, *inter alia*, disregarded the

[17] Under the special factor test, *supra*, market rates should be awarded to certain identified counsel. Under the bad faith basis, market rates should be awarded to all counsel as explained herein.

Circuit's controlling law and its conduct in litigating the matter was for reasons of delay). District courts may also consider pre-litigation conduct in making a determination that there was bad faith sufficient to justify a fee award. *See Kerin*, 218 F.3d at 195-96.

The actions of the government in this case are the epitome of bad faith meriting an appropriate fee award. *Tummino II*, at *75 ("bad faith…has permeated the FDA's consideration of the Citizen Petition from beginning to end"); *see also id.* at *100 ("strong showing of bad faith" justified consideration of materials outside of administrative record.) The entire litigation was necessary and prolonged because of the government's improper conduct; therefore, Plaintiffs are entitled to the full amount of their attorneys' fees as this is the amount necessary to counter the government's bad faith. *See Kerin*, 218 F.3d at 192-93. Therefore, Plaintiffs are entitled to attorneys' fees at prevailing market rates for all legal services provided in this matter. *Id.* at 193.

**a. The Government's Actions Were Meritless**

The government's actions are meritless when lacking any legal or factual basis. *Kerin*, 218 F.3d at 190. For many of the same reasons the government's conduct was substantially unjustified as lacking any reasonable basis in fact or law, *see* Section I.B., *supra*, the government's egregious conduct was also meritless for purposes of an award of fees pursuant to the bad faith exception. The government's conduct in this case – both which necessitated the litigation, as well as its conduct throughout the litigation – was based on improper political decision making completely at odds with the proper function of a major government agency designated to protect the health of the American public. The Administration made political decisions interfering with the health and safety of American women and girls and used U.S.

taxpayer funds to pursue and defend these acts that were the essence of bad faith. Two federal agencies defied their regulatory and procedural obligations, acting in abrogation of their duties.

In 2009, the District Court concluded that the FDA's denial of the Citizen Petition was "arbitrary and capricious" and "not the result of reasoned and good faith agency decision-making." *Tummino I*, at 523. The Court remanded to the agency to reconsider the Citizen Petition, but directed the FDA "to make Plan B available to 17 year olds without a prescription," finding that "[a] remand would serve no purpose" because the exclusion of 17 year olds "runs counter to the evidence and is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*, at 549-50 (internal quotation marks omitted).

On remand, Defendants' conduct was plagued by bad faith and undue delay. Defendants relied on arguments and certain evidence in support of their claims in this case which were previously addressed and rejected by this Court in *Tummino I* related to the Plaintiffs' standing and the FDA's failure to extrapolate. *Tummino II*, at *8, n.3, 37-48. These arguments were found to be just as lacking here as they were in *Tummino I*. *Id.* Plaintiffs were forced to expend time and resources to address the government's bad faith obstruction and litigation tactics. The Court's orders in *Tummino II* and *Tummino III* detail the complete lack of factual or legal basis for the government's position in this litigation. The Court was put in the extraordinary position of being asked by the FDA, the very agency whose authority was usurped unlawfully by the Secretary, to approve of this scientifically unjustified and politically motivated departure from laws and regulations governing the drug approval process. *Tummino II*, at *10-13. The government's "flagrant misconduct" is the reason the Court declined to remand the Citizen Petition because the government could not provide "any assurance that the result [on remand] would be any different." (ECF No. 98 at 16.)

The government's conduct was found to be scientifically unjustified and contrary to agency precedent, demonstrating the complete lack of any factual or legal support for Defendants' position in this case. *Tummino II*, at*18-63, 73-87. Even though this case "involves the interpretation of a general statutory and regulatory scheme relating to the approval of drugs for over-the-counter sale[,]" the standards for which are the same for aspirin as for contraceptives, *id.*, at *17, the government's denial of the SNDA and Citizen Petition "was accomplished by unexplained departures from a number of established policies and practices followed by the FDA." *Id.*, at *20.

The Court found that "the most significant departure from agency practice was the intervention of the Secretary of Health and Human Services." *Id.*, at *21. The reasons she gave for this intervention were "so unpersuasive as to call into question her good faith." *Id.*, at *23. The Court found that her decision was not entitled to the deference due to the FDA "as a result of its specialized expertise and judgment" because she has no specialized technical expertise and that the Secretary was either "unaware" of the FDA's drug approval procedures or "she consciously ignored them." *Id.*, at *66-67. The Secretary's failure to acknowledge, much less explain, these deviations in policy made it clear that it was not the type of decision deserving of deference because it was not made by the Commissioner, whom Congress entrusted the responsibility to make the necessary scientific judgment. *Id.*, at *70-72 ("Indeed it is hardly clear that the Secretary had the power to issue the order, and if she did have that authority, her decision was arbitrary, capricious, and unreasonable.") Defendants' complete failure to provide a good faith rationale for its deviations in policy further evidences its bad faith conduct. The Secretary's positions, in particular, were undefended and Defendants' positions, in general, were indefensible.

In reviewing the government's denial of the Citizen Petition, the Court also found other evidence of the government's meritless claims. The government was deceptive about the scientific evidence it had before it. *Id.*, at *77-87. This provided a separate basis for denial of the Citizen Petition based on the government's "disregard for the scientific evidence that the FDA had before it." *See also Tummino III*, at *5 ("The Citizen Petition Denial Letter…was clearly prompted by the Secretary's action despite the FDA's fanciful effort to make it appear that it undertook an independent review of the Citizen Petition.") The Defendants' deceptions in the course of the litigation are further evidence of its bad faith conduct. The government's conduct following the *Tummino II* decision was just as meritless as its position throughout the litigation. First, "in something of an alternate reality" the government sought a stay of an order that restored the FDA's scientific integrity "to pursue an appeal that would vindicate the Secretary's disregard of the very principle they advocate." *Id.*, at *9. Furthermore, after this Court held that "the FDA did not have the authority to mandate point-of-sale restrictions on drugs approved for nonprescription sales that it found to be safe and effective for all women of childbearing age," the FDA persisted in this policy. In its attempt to sugar coat its appeal, it approved Teva's amended SNDA which would have resulted in "a convoluted triple-tiered marketing scheme that will only increase the confusion that already prevents women from obtaining timely access to emergency contraceptives." *Id.*, at 23.

This Court expressed its opinion that the appeal was "frivolous" on the merits, and ultimately the appeal was voluntarily dismissed by Defendant after the Second Circuit denied the Stay as to two-pill emergency contraception products. The Defendants' persistence in pursuing unsupported and meritless positions that continued to consume litigation and judicial resources is further evidence of its bad faith conduct.

**b. The Government's Conduct was Undertaken for the Improper Purposes of Delay and Political Interference in the FDA's Drug Approval Process**

The government's conduct on remand following *Tummino I*, in the District Court during contempt proceedings, in *Tummino II* and then on appeal were permeated by the improper purposes of delay and political interference in the FDA's drug approval process. Indeed, these improper purposes infected the government's entire decision making process concerning the over-the-counter switch of emergency contraception, including the reconsideration of the Citizen Petition.

As this Court acknowledged, the course of this litigation "most of the time" has been due to the agency's delay. (Tr. of April 27, 2012, 141:21-23); *see also Tummino II*, at *58 (referring to approval process of Plan B's dual marketing regime as "long and tortured"). *Tummino I* was filed to compel the FDA to make a decision on the citizen's petition. (*Id.* at 141:23-24.) It was not until June of 2006 that the FDA finally made a decision by denying the Citizen Petition five years after it had been filed. *Tummino I*, at 536. Even though the FDA had effectively made a decision on the Citizen Petition at the time it denied the Plan B sponsor's first SNDA, it waited more than two years (and after a lawsuit was filed) to communicate that decision to Plaintiffs. *Id.* at 536-37.

On remand, for almost three years, the FDA refused to take any steps to reconsider the Citizen Petition. *Tummino II*, at *10-11. Instead, the agency informed Plaintiffs that it believed that "the best way" to comply with the order was "to review a supplemental new drug application expected to be submitted by the sponsor of [Plan B One-Step]" for over-the-counter access for all ages. *See* Letter from Frank Amanat to Suzanne Novak (Aug. 13, 2010), Case No. 05-CV-366 (ERK/VVP), ECF No. 307-3. The denial of the Citizen Petition finally came on the eve of a

hearing on Plaintiffs' Motion for Contempt. (ECF No. 2 at 25.); *see also Tummino III*, at *4 ("The FDA, responding to unjustified political interference, delayed as long as it possibly could before it took even one incremental step in the process.")

The government's "intolerable delays in processing the [Citizen] Petition" were cited by this Court as justification for declining to remand to the FDA for rulemaking:

> [E]ven if the defendants' arguments would be sufficient to carry the day in the run-of-the-mill case, the bad faith that has permeated consideration of the Citizen Petition, not to speak of the Plan B sponsor's applications, should rule out such relief here. More than twelve years have passed since the Citizen Petition was filed and eight years since this lawsuit commenced. The FDA has engaged in intolerable delays in processing the petition. Indeed, it could accurately be described as an administrative agency filibuster. Moreover, one of the devices the FDA has employed to stall proceedings was to seek public comment on whether or not it needed to engage in rulemaking in order to adopt an age-restricted marketing regime. After eating up eleven months, 47,000 public comments, and hundreds of thousands, if not millions, of dollars, it decided that it did not need rulemaking after all. The plaintiffs should not be forced to endure, nor should the agency's misconduct be rewarded by, an exercise that permits the FDA to engage in further delay and obstruction.

*Tummino II*, at *105-06.

Even after this Court's Order, the government did not comply and instead filed an appeal and a motion to stay "as they continue[d] their administrative agency filibuster through the appeal process." *Tummino III*, at *8. The government relied on its approval of an amended SNDA by Teva to argue that Plaintiffs would not suffer harm because the FDA had lowered the age to purchase Plan B One-Step over-the-counter from seventeen to fifteen years of age. *Id.*, at 11-12. This application was approved the day before Defendants filed their notice of appeal. *Id.*, at 11. The timing of the approval, and the lack of explanation by the FDA as to why it delayed more than a year in approving this application, led this Court to conclude that it was "intended to provide a sugarcoating for the FDA's appeal." *Id.*, at *11-12*; see also id.*, at 31 (appeal "taken for the purpose of delay").

After the Defendants' stay was denied by the Second Circuit as to two-pill products, but granted as to one-pill products, Defendants' could no longer delay making some form of emergency contraception available over-the-counter without age or point-of-sale restrictions. But, instead of making two-pill products available over-the-counter, Defendants notified this Court that they planned to comply with the ruling by only making Plan B One-Step available OTC. Defendants, after delaying for twelve long years, were finally thwarted in this improper purpose.

In addition to the "intolerable delays", Defendants' conduct in this action was taken for improper purpose by allowing, and defending, unprecedented political interference in the drug approval process. Even though there was political interference throughout the course of the government's decision-making process on emergency contraception, *see generally Tummino I*, the Secretary's overruling of the Commissioner's decision to approve Teva's SNDA for Plan B One-Step was a flagrant departure from the drug approval process. *Tummino III*, at *8.

The unprecedented intervention of the Secretary was "obviously political." *Tummino II*, at *23 ("It was the first time a cabinet member had ever publicly countermanded a determination by the FDA") (citations omitted); *see also* Tr. of April 27, 2012, 18:15-17 (counsel for Teva referring to the Secretary's "unprecedented historical involvement" in the decision to deny its SNDA). It was "an election year decision that many public health experts saw as a politically motivated effort to avoid riling religious groups and others opposed to making birth control available to girls." *Tummino II*, at *23 (citations omitted).

The government's improper political purpose was also evident when it fabricated a "complete pretext" which was yet "another example of the bad faith that has permeated the FDA's consideration of the Citizen Petition from beginning to end" by falsely claiming that the

Plaintiffs had to provide "additional data" comparable to that in the Plan B One-Step application when any such data was rejected by the government for reasons found to be "politically motivated, scientifically unjustified, and contrary to agency precedent." *Tummino II*, at *86. The FDA's Citizen Petition denial letter was "composed mainly of filler that was designed to create the illusion that it was engaging in some independent exercise of agency discretion." *Tummino II*, at *74.

An article published in the New England Journal of Medicine by three distinguished scientists opined that "the secretary's decision to retain behind-the-counter status for Plan B One-Step was based on politics rather than science. It cannot be based on issues of safety…Any objective review makes it clear that Plan B is more dangerous to politicians than to adolescent girls." *Id.* The Court's Order reversing the Secretary's decision and directing the Defendants to grant the Citizen Petition was issued because "the Secretary's action was politically motivated, scientifically unjustified, and contrary to agency precedent, and because it could not provide a basis to sustain the denial of the Citizen Petition." *Tummino III*, at *6.

In their Motion for Stay, Defendants did not argue they had any possibility of success in challenging this finding on appeal. *See id.*, at n. 1. Defendants argued that the public interest would be harmed if a drug were approved by the Court instead of by the FDA. This Court rejected that argument, finding that since the Commissioner had found the drug was safe and was prepared to make it available over-the-counter to all ages, "the public can have confidence that the FDA's judgment is being vindicated." *Id.*, at *21. However, if a stay were to be granted, the Court stated "it will allow the bad-faith, politically motivated decision of Secretary Sebelius, who lacks any medical or scientific expertise, to prevail—thus justifiably undermining the public's confidence in the drug approval process." *Id.* Further, this Court took issue with

Defendant's claim that the Court exceeded its authority in issuing a directive instead of remanding to the agency because the Court did not believe the government could be trusted to make a fair assessment of the scientific evidence based on the Secretary's interference. *Id.*, at *29-30 ("On remand, defendants engaged in the same bad faith that resulted in my initial remand. They delayed the decision for three years, and ultimately, improper political influence prevented the FDA from granting the petition.")

In sum, there is overwhelming evidence in the record that the government's conduct in this litigation was undertaken for improper purpose. *Kerin*, 218 F.3d at 191-92. This Court has already made detailed findings of the government's "intolerable delays" and flagrant and unprecedented political interference in the drug approval process. These improper motives, together with Defendants' meritless position (discussed *supra*), demonstrate that a bad faith award is justified. *Id.* at 192. At the heart of the government's bad faith conduct is the fact that the Defendants disregarded and jeopardized the health and safety of millions of American women and girls for over a decade and only through Plaintiffs' efforts was this conduct forced to cease.

Plaintiffs' bad faith fees calculations are as follows (including all counsel):

| **Attorney** | **Law School Graduation** | **Requested Rate** | **Hours** | **Total** |
|---|---|---|---|---|
| Janet Crepps | 1983 | $650 | 117.1 | $76,115 |
| Suzanne Novak | 1997 | $560 | 449.3 | $251,608 |
| Andrea Costello | 1998 | $560 | 305.2 (PCJF)<br>51.3 (FILS) | $170,912 (PCJF)<br>$28,728 (FILS) |
| Kirsten Clanton | 2005 | $450 | 131.4 | $59,130 |
| Natalie Maxwell | 2005 | $450 | 26.6 | $11,970 |

| | | | | |
|---|---|---|---|---|
| Mara Verheyden - Hilliard | 1994 | $600 | 43.2 | $25,920.00 |
| Carl Messineo | 1994 | $600 | 17.8 | $10,680 |
| Fried Frank Attorneys and Paralegal[18] | | | 747.1 | $330,494.40 |
| Candice Kalis | Paralegal and 2012 Law School Graduate (PCJF) | $90 | 16.7 | $1,503.00 |
| | | | **LODESTAR TOTAL:** | **$967,060.40** |

### III. Plaintiffs' Claimed Costs are Recoverable Under the EAJA

The EAJA allows a prevailing party to recover "fees and other expenses" associated with litigating its claim. 28 U.S.C. § 2412(d)(2)(A). The Second Circuit has found costs to be broadly recoverable under the EAJA, including all out-of-pocket costs that are ordinarily billed to a client, such as photocopying and transcript costs. *Aston v. Sec'y of Health and Human* Services, 808 F.2d 9, 12 (2d Cir. 1986).

In this case, Plaintiffs expended $1,081.82 in reimbursable costs before the District Court and these amounts should be awarded to them as part of the Court's order. *See* Costello Decl., Ex. A and Crepps Decl., Ex. B.

## CONCLUSION

For the foregoing reasons, the Court should order fees and costs in the amount that Plaintiffs have requested.

[18] *See* n. 8, *supra*. Fried Frank has applied a 10% discount for the market rate fees total for its counsel and paralegals that performed work in this litigation. *See also* Mac Avoy Decl., ¶ 5, for years of graduation for each Fried Frank counsel.

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Respectfully submitted,

/s/ Andrea Costello

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